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Addressing Lead at Superfund Sites

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Frequent Questions from Risk Assessors on the Adult Lead Methodology (ALM)

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General Questions

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What is the receptor population for the Adult Lead Methodology?

In the commercial/industrial setting, the most sensitive receptor is the fetus of a worker who develops a body burden as a result of non-residential exposure to lead. This body burden is available to transfer to the fetus for several years after exposure ends (Gulson et al., 1998; Gulson et al., 1999). Based on the available scientific data, a fetus is more sensitive to the adverse effects of lead than an adult (National Academy of Sciences, 1993). We assume that cleanup goals (preliminary remediation goals or PRGs) that are protective of a fetus will also afford protection for male or female adult workers. The model equations were developed to calculate cleanup goals such that there would be no more than a five per cent probability that fetuses exposed to lead would exceed a blood lead (PbB) of 10 micrograms lead per deciliter of blood (µg/dL). This same approach also appears to be protective for lead's effect on blood pressure in adult males (see Adult Lead Methodology Review Report available from the Software and Users' Manuals page).

Does the Adult Lead Methodology calculate a value for a commercial worker or an industrial worker?

The adult lead methodology does not distinguish between commercial and industrial workers; rather, it is applicable to non-residential exposure scenarios. According to EPA's guidance on the adult lead methodology, a soil ingestion rate of 50 mg/day is recommended as a plausible central tendency value for non-contact-intensive activities (U.S. EPA, 1997). Either commercial or industrial workers may work primarily indoors, so that exposure to soil occurs primarily via indoor dust. Workers' limited and occasional contact with outdoor soils (e.g., picnicking, walking to parking lots, standing on a loading dock) should be adequately accounted for via the 50 mg/day incidental soil ingestion. If an individual is performing a contact-intensive activity with soil, then a soil ingestion rate greater than 50 mg/day would be expected. At sites where lead materials have been historically used, exposure scenarios would have to be evaluated individually to determine the indoor and outdoor activities that may result in greater exposure to soil and the corresponding soil ingestion rate.

What is a reasonable screening value for soil lead at commercial/industrial sites?

A screening goal is often more protective than a cleanup goal. A screening goal is intended to provide health protection without knowledge of the specific exposure conditions at a site. A cleanup goal can be derived using exposure assumptions based on site-specific data rather than default values (which are often more conservative). An updated screening level for soil lead at commercial/industrial (i.e., non-residential) sites of 800 part per million (ppm) is based on a recent analysis of the combined phases of the National Health and Nutrition Examination Survey (NHANES III) that choose a cleanup goal protective for all subpopulations.

What is a reasonable baseline blood lead level (PbB_0) to use for a future exposure scenario?

Although the best estimates for PbB_0 are based on site-specific data, such information may not be available for a future exposure scenario. Application of this value should consider the proportion of each population (present on the site or anticipated in the future) as defined by the National Health and Nutrition Examination Survey (NHANES III) study and as described in the recommendations of the TRW for use of the NHANES III data for adult lead risk assessment (see section 3.4, page 9 of NHANES report, available from the Guidance page). For site applications of the adult lead methodology, estimates of the $PbB_{adult,0}$ and $GSD_{i,adult}$ parameters could be based on either race/ethnicity or geographic categories determined appropriate based on the specific demographic or geographic characteristics of the site. Because of the small sample sizes that result, the Technical Review Workgroup for Metals and Asbestos (TRW) recommends that users do not use data from the NHANES III survey that are stratified by both census region and race/ethnicity group to derive $PbB_{adult,0}$ and $GSD_{i,adult}$.

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Input Variables

- What is an appropriate geometric standard deviation (GSD) for my site?
- Should I assume that the indoor dust lead level is the same as the outdoor soil (dust) lead concentration when I run the model?
- What is the appropriate exposure frequency for a typical commercial/industrial worker -- 250 days, 219 days, or some other derived value for intermittent exposure?
- Is soil lead (from Equation 1) the site soil concentration to which the adult is exposed?
- What is an appropriate soil ingestion rate for a construction scenario (i.e., soil contact-intensive scenario)?

What is an appropriate geometric standard deviation (GSD) for my site?

The GSD blood lead (PbB) for a population is a measure of inter-individual variability of observed blood lead levels. Factors that may contribute to variability in a population include:

- occupational exposure
- exposure history
- socioeconomic and ethnic characteristics
- activity patterns
- degree of urbanization
- geographic location
- sources of lead

A homogeneous population (i.e., expected to have a low GSD) may have similar characteristics and exposure histories, and live within a small geographic area; there may be a single dominant source of lead exposure (e.g., an ethnically and culturally homogeneous population living in a small town). By contrast, individuals with diverse backgrounds, who are exposed to multiple sources of lead within an urban community, may be considered a heterogeneous population.

In the absence of information that would indicate whether the population is homogeneous or heterogeneous, an appropriate geometric standard deviation (GSD) value would be based on analysis of the combined phases of NHANES III across all quadrants appropriate for the site. For site applications of the adult lead methodology, estimates of the $PbB_{adult,0}$ and $GSD_{i,adult}$ parameters could be based on either race/ethnicity or geographic categories determined appropriate for the site.

Because of the small sample sizes that result, the Technical Review Workgroup for Metals and Asbestos (TRW) recommends against the use of data from the NHANES III survey that are stratified by both census region and race/ethnicity group to derive $PbB_{adult,0}$ and $GSD_{i,adult}$.

Important considerations include the present and future ethnicity of the exposed population, future land uses or development plans if available, whether any sensitive groups are present, and whether any major future changes in population are anticipated.

Should I assume that the indoor dust lead level is the same as the outdoor soil

(dust) lead concentration when I run the model?

An appropriate assumption is that the concentration of lead in (sieved) outdoor soil and indoor soil-derived dust is the same. This is not the same as assuming the concentration of lead in outdoor soil and all sources of dust (i.e., aggregate dust) are equal. The concentration of lead in aggregate dust may reflect a combination of outdoor soil, indoor lead sources (e.g., paint), and non-lead sources (e.g., organic material). Since the default assumption for the model is that soil ingestion represents outdoor soil and indoor soil-derived dust only (without contributions from other sources of lead), no distinction is needed between soil and dust concentrations.

What is the appropriate exposure frequency for a typical commercial/industrial worker -- 250 days, 219 days, or some other derived value for intermittent exposure?

The model default value for exposure frequency (EF) is 219 days/year. This value is a central tendency estimate for non-residential exposure scenarios (i.e., both commercial and industrial), and corresponds to the average time spent at work by both full- and part-time workers engaged in non-contact-intensive activities. If workers are engaged in full-time activities, then an EF greater than 219 days/year may be appropriate. The adult lead methodology is designed to estimate blood lead concentrations (PbB) for workers who have a sustained period of contact with exposure media. The default assumption for the averaging time (AT) is one year (365 days), which is sufficient time for PbB to approach quasi-steady state (see Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil, December 1996). If exposures are expected to occur over a shorter time interval, then EF should not be prorated over the entire year. For example, average daily lead intake from soil for a construction worker who works five days a week on a 26-week construction project and is not on site during the other 26 weeks (EF=130 days) would be assessed using an averaging time of 26 weeks (AT=182 days) rather than 52 weeks to avoid "diluting" the exposures over the entire year.

Is soil lead (from Equation 1) the site soil concentration to which the adult is exposed?

Yes, the soil lead in Equation 1 refers to the exposure point concentration. In most cases, exposure is assumed to be predominantly to the top layers of the soil (the recommendation is the top two centimeters); however, if that is not representative or available then the most shallow samples of contaminated soil that can be collected under site conditions (see EPA Soil Screening Guidance, 1996) which give rise to transportable soil-derived dust should be considered. Exposure to soil-derived dust occurs in both outdoor and indoor environments, the latter occurring where soil-derived dust has been transported indoors. The model accounts for exposures that occur on a regular basis. Under both current and future exposure scenarios, an arithmetic mean concentration should be estimated from sampling data within the exposure area that a worker would be expected to have access to on a regular basis. Half an acre is a reasonable default assumption. Site-specific information may suggest workers are exposed to a greater area (e.g., lineman) or a smaller area (e.g., small commercial facility site).

What is an appropriate soil ingestion rate (IR) for a construction scenario (i.e., soil contact-intensive scenario)?

The TRW recommends 50 mg/day as the default ingestion rate for indoor workers. This value is cited in the ALM guidance (Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil, December 1996), and the Exposure Factors Handbook (U.S. EPA, 1997). A reasonable default value that has been commonly used as a central tendency estimate for contact-intensive adult scenarios (such as an agricultural or construction worker) is 100 mg/day.

There is high uncertainty in soil ingestion rates for adults due to sparse empirical data on adult soil ingestion rates. There are data available from two studies (Calabrese et al., 1990; Calabrese et al., 1997), each conducted concurrently with a study of childhood soil ingestion rates, but neither study group targeted a population expected to engage in frequent contact with soil, such as construction workers. The purpose of the studies was to verify the tracer mass balance methodology used in the child studies. Despite their limitations, these studies provide an estimate of the amount of soil ingested by adults.

The value of 50 mg/day represents a reasonable central tendency estimate of adult soil ingestion based on available data and is the recommended mean value. The value of 100 mg/day is equal to the recommended mean soil IR for young children, whose daily ingestion rates are expected to exceed that of adults (U.S. EPA, 1997). For construction workers and other soil contact-intensive occupations, Office of Solid Waste and Emergency Response (OSWER) guidance recommends an upper bound value for IRs of 330 mg/day based on Stanek et al. (1997) (as cited by EPA's Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites, 2001). The basis of the default IR is the 95th percentile value (330 mg/day). In this study, Stanek et al. (1997) also report the median, 75th percentile, and mean values as one, 49, and 10 mg/day (SD = 94), respectively. The coefficient of variation value of 9.4 is indicative of significant uncertainties in these estimates.

Because central tendency values are recommended as inputs to both the IEUBK Model and the adult lead methodology, a more plausible range for a soil lead IR is 50 to 200 mg/day for adult contact-intensive soil exposures. Thus, there is reasonable support for use of 100 mg/day as a soil ingestion rate for the contact-intensive worker scenario in the ALM.

Soil IRs can be compared to measures of soil adherence to hands to provide additional perspective. Soil adhered to hands is relevant to soil ingestion because it is available for ingestion from hand-to-mouth activities; however, an accepted methodology that reliably estimates soil ingestion using soil adhesion data has not been developed for hazardous waste risk assessments.

Application

- What is the shortest period of time for which I can apply the adult lead methodology?
- Can the Adult Lead Methodology (ALM) be used to estimate adolescent trespassing? How would the ALM be applied when the receptor is an adolescent? What baseline blood lead level is appropriate? What about other input parameter values?
- Is 10 µg/dL (in the construction scenario) a level that should never be exceeded?
- Can the adult lead methodology be used to determine dermal exposure to lead at a site?

- Should sieving be used to characterize samples for non-residential sites?
- Can the Adult Lead Methodology (ALM) be used to evaluate dietary lead exposures, specifically fish ingestion exposures?

What is the shortest period of time for which I can apply the adult lead methodology?

The exposure duration (ED) should be sufficiently long to allow blood lead concentrations (PbB) to approach quasi-steady state. As discussed in the guidance, the shortest period of time appropriate for ED is three months (90 days). A minimum frequency of exposure of 1 day per week is also recommended. The ALM is recommended for repeated intermittent or continuous exposures over extended periods of time; it should not be used for acute exposures.

Can the Adult Lead Methodology (ALM) be used to estimate adolescent trespassing? How would the ALM be applied when the receptor is an adolescent? What baseline blood lead level is appropriate? What about other input parameter values?

The adolescent population may be considered sensitive since exposures during these years may result in a body burden of lead that is available to transfer to the fetus later in life. Given the limitations of currently available modeling tools, it is reasonable to apply the ALM to adolescent receptors (e.g., trespasser scenarios), provided that appropriate values can be selected for the following important model parameters:

- exposure frequency (EF)
- exposure duration (ED)
- baseline blood lead (PbB₀)
- absorption fraction (AF)

Although empirical data on biokinetic slope factors (BKSF) appear similar for young children and adults, uncertainty arises when applying a similar estimate for adolescence (Mahaffey et al., 1998).

In addition, selecting an appropriate baseline blood lead (PbB₀) is likely to be difficult. Brody et al. (1994) reported low PbB₀ for children ages 12 to 18 years (which results in preliminary remediation goals ranging from 1800 to 2000 ppm). The low PbB₀ may be due to a growth spurt in which there is an increase in bone deposition that results in a lower concentration of lead in the blood; the total body burden of lead may still be increasing (Muth and Globel, 1983). Other factors may also contribute, such as increases in blood volume during periods of rapid growth. There is also a potential that lead absorption will be higher in adolescents than in adults.

National databases (e.g., NHANES III) can provide quality information on PbB₀. Presentation of calculations using a range of PbB₀ values is recommended.

Is 10 µg/dL (in the construction scenario) a level that should never be exceeded?

No. The 10 µg/dL is a multi-Agency goal that has been designated by the U.S. Centers for Disease Control (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) as a level of concern to protect sensitive populations (neonates, infants, and children). The protection of sensitive populations is assumed to also provide protection for adults. EPA's stated goal for lead is that children (up to 84 months of age) exposed at a risk-based cleanup level would have no more than a five per cent probability of exceeding the level of concern (U.S. EPA, 1994; U.S. EPA, 1998). The adult lead methodology extends that same concept to develop cleanup goals preventive of fetal risk. As a statistical goal, a probability of exceedance of up to five per cent of the goal is acceptable.

Can the adult lead methodology be used to determine dermal exposure to lead at a site?

Although percutaneous absorption is generally not a significant route of exposure for inorganic lead, technically, the model can evaluate dermal exposure by incorporating the lead uptake from this pathway into the appropriate equation (see Equation A-3 in the Guidance). However, at this time, quantifying uptake from dermal exposure to soil-borne lead is not recommended due to the uncertainty in assigning a dermal absorption fraction that would apply to the numerous inorganic forms of lead that are typically found in environmental settings.

Should sieving be used to characterize samples for non-residential sites?

The lead concentration in the sieved (250 micron) fraction of surface soil provides the best estimate of the soil lead that is incidentally ingested and should be used in the ALM. However, sieving of samples from all depths may be useful in site characterization; users should proceed with caution when developing ratios between sieved and unsieved samples.

- Download the Sieving Short Sheet [EPA-540-F-00-010] (PDF) (3 pp, 81K, About PDF)

Can the Adult Lead Methodology (ALM) be used to evaluate dietary lead exposures, specifically fish ingestion exposures?

Yes, but only when reliable site-specific information on fish ingestion and bioavailability for the lead in fish is known. This approach might be applicable to a local or regional source of lead that is not accounted for in nationally based recommendations regarding baseline lead levels, which consider commercially available fish species and average fish consumption rates. The addition of a specific fish exposure pathway may result in a slight overestimate of risk as a result of double-counting of dietary lead, because normal dietary exposure to lead in fish is already accounted for by the baseline blood lead concentration (PbB0) (see NHANES report available from the Guidance page).

The ALM analysis could be performed to evaluate the local fish contribution to lead exposure. A fish advisory could also be developed by applying the ALM in reverse to derive an upper-bound ingestion rate for a given lead concentration in fish tissue, using an increasing intake

of fish to determine an intake corresponding to a target risk level (e.g., P10 of five per cent). For bioavailable fraction of lead in fish (AFF), a protective estimate of 12% would be appropriate (James et al., 1985; Blake et al., 1983). Site-specific information should be used along with the NHANES guidance and the Exposure Factors Handbook in developing the site-specific exposure scenario.

The equation from the ALM can be used (with the following modifications) to calculate overall risk posed by consuming fish that are contaminated with lead:

$$PbB = (Pb_S \times BKSF \times IR_{S+D} \times AF_{S,D} \times EF_S/AT_{S,D}) + (Pb_F \times BKSF \times IR_F \times AF_F \times EF_F/AT_F) + PbB_0$$

where:

i = media (soil [_S], soil and dust [_{S,D}], or fish [_F])

Pb_i = Media lead concentration (µg/g) (appropriate average concentration)

IR_i = Intake rate (g/day)

AF_i = Absolute gastrointestinal absorption fraction for ingested lead in media (unitless)

EF_i = Exposure frequency (days/year)

PbB_0 = Baseline blood lead (µg/dL)

BKSF = Biokinetic slope factor

AT_i = Averaging time (days/year)